



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0775. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

OMB Control Number 0910-0775--Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 201(rr) of the FD&C Act (21 U.S.C.321(rr)), as amended, defines a tobacco product as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

Section 910 of the FD&C Act (21 U.S.C. 387j) sets out premarket requirements for new tobacco products. The term new tobacco product is defined as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any

other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976).

FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products. Grandfathered tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document associated with this information collection provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A grandfathered tobacco product may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)(A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i))).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the

following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

In the *Federal Register* of October 17, 2018 (83 FR 52488), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, they were not PRA related.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FD&C Act Sections or Action	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	1,000	1	1,000	5	5,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the grandfathered status of a tobacco product under the guidance is not required and also on the number of grandfathered submissions received from 2011 to June 2018. We estimate submissions have increased due to the effective date of the deeming rule. FDA has stated that, for deemed combustible products that were on the market as of August 8, 2016, it does not intend to initiate enforcement for failure to have premarket authorization until August 8, 2021. FDA has also stated that, for deemed noncombustible products that were on the market as of August 8, 2016, it does not intend to initiate enforcement for failure to have premarket authorization until August 8, 2022. Because interested persons are seeking information on the grandfathered status of tobacco products in advance of these dates, FDA expects a drop in the number of grandfathered submissions following those dates. The number of hours to gather the

evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 5,000 hours annually to respond to this collection of information.

Our estimated burden for the information collection reflects an overall increase of 4,235 hours. We attribute this adjustment to an updated number of submissions received through this approval and the number of submissions expected in the next 3 years.

Dated: May 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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